eligibility for patent term restoration. In a letter dated January 29, 1999, FDA advised the Patent and Trademark Office that this human biological product had undergone a regulatory review period and that the approval of Regranex® and Becaplermin Concentrate represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Regranex® and Becaplermin Concentrate is 2,790 days. Of this time, 2,424 days occurred during the testing phase of the regulatory review period, while 366 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: April 29, 1990. The applicant claims March 30, 1990, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 29, 1990, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human biological product under section 505 of the act*: December 16, 1996. FDA has verified the applicant's claim that the product license applications (PLA's) for Regranex® (PLA 96–1408) and Becaplermin Concentrate (PLA 96–1422) were initially submitted on December 16, 1996.

3. *The date the application was approved*: December 16, 1997. FDA has verified the applicant's claim that PLA 96–1408 and PLA 96–1422 were approved on December 16, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,593 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before May 3, 1999, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before August 31, 1999, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 16, 1999.

Thomas J. McGinnis,

Deputy Associate Commissioner for Health Affairs.

[FR Doc. 99–5388 Filed 3–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Notice of Meetings

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a tentative schedule of forthcoming meetings of its public advisory committees for 1999. At the request of the Commissioner of Food and Drugs (the Commissioner), the Institute of Medicine (the IOM) conducted a study of the use of FDA's advisory committees. The IOM recommended that the agency publish an annual tentative schedule of its meetings in the **Federal Register**. In response to that recommendation, FDA is publishing its annual tentative schedule of meetings for 1999.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4820.

SUPPLEMENTARY INFORMATION: The IOM, at the request of the Commissioner, undertook a study of the use of FDA's advisory committees. In its final report, the IOM recommended that FDA adopt a policy of publishing an advance yearly schedule of its upcoming public advisory committee meetings in the **Federal Register**. FDA has implemented this recommendation. A tentative schedule of forthcoming meetings will be published annually in the **Federal Register**. The annual publication of tentatively scheduled advisory committee meetings will provide both advisory committee members and the public with the opportunity, in advance, to schedule attendance at FDA's upcoming advisory committee meetings. The schedule is tentative and amendments to this notice will not be published in the **Federal Register**. FDA will, however, publish a **Federal Register** notice 15 days in advance of each upcoming advisory committee meeting, announcing the meeting (21 CFR 14.20).

The following list announces FDA's tentatively scheduled advisory committee meetings for 1999:

Committee Name	Dates of Meetings	Information Line Code
OFFICE OF THE COMMISSIONER		
Science Board to the Food and Drug Administration	June 11 September 14	12603
CENTER FOR BIOLOGICS EVALUATION AND RESEARCH		
Allergenic Products Advisory Committee	February 22 October 26	12388
Biological Response Modifiers Advisory Committee	March 18–19 July 15–16 November 18–19	12389

Committee Name	Dates of Meetings	Information Line Code
Blood Products Advisory Committee	March 25–26 June 17–18 September 16–17 December 9–10	19516
Transmissible Spongiform Encephalopathies Advisory Committee	June 2–3 November 8–9	12392
Vaccines and Related Biological Products Advisory Committee	January 29 March 11 May 10–11 July 8–9 September 14–15 November 4–5	12391
CENTER FOR DRUG EVALUATION AND RESEARCH		
Advisory Committee for Pharmaceutical Science	May 20–21 August 19–20	12539
Advisory Committee for Reproductive Health Drugs	March 18–19 September 16–17	12537
Anesthetic and Life Support Drugs Advisory Committee	January 12 May 10–11 September 13–14 December 9–10	12529
Anti-Infective Drugs Advisory Committee	March 4 July 29–30 December 1–2	12530
Antiviral Drugs Advisory Committee	February 24 May 3–5 July 26–28 September 13–15	12531
Arthritis Advisory Committee	February 23 April 20–21 July 20–21 September 21–22 November 30 December 1	12532
Cardiovascular and Renal Drugs Advisory Committee	January 28–29 April 29–30 July 26–27 October 14–15	12533
Dermatologic amd Opthalmic Drugs Advisory Committee	April 16 June 17–18 August 12–13 October 28–29 December 9–10	12534
Drug Abuse Advisory Committee	April 20 July 8–9 September 20–21	12535
Endocrinologic and Metabolic Drugs Advisory Committee	March 26 May 20–21 July 8–9 September 16–17 November 18–19	12536
Gastrointestinal Drugs Advisory Committee	May 6–7 September 16–17	12538
Medical Imaging Drugs Advisory Committee	June 21–22	12540
Nonprescription Drugs Advisory Committee	March 23 April 15–16 July 19–20 October 18–19 December 2–3	12541
Oncologic Drugs Advisory Committee	January 12–13 March 22–23 June 7–8	12542
Peripheral and Central Nervous System Drugs Advisory Committee	April 28–30 September 23–24	12543
Pharmacy Compounding Advisory Committee	May 6–7	12440
Psychopharmacologic Drugs Advisory Committee	June 1–2	12544
Pulmonary-Allergy Drugs Advisory Committee	May 27–28	12545

Committee Name	Dates of Meetings	Information Line Code
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION		
Food Advisory Committee	April 26–28 August 4–6 November 18–19	10564
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH		
Device Good Manufacturing Practice Advisory Committee	No meetings planned	12398
Medical Devices Advisory Committee		
Anesthesiology and Respiratory Therapy Devices Panel	March 5 June 25 August 27 November 12	12624
Circulatory System Devices Panel	March 1–2 June 2–3 September 13–14 December 9–10	12625
Clinical Chemistry and Clinical Toxicology Devices Panel	February 26 April 30 September 23–24 December 6	12514
Dental Products Panel	June 8–9 August 10–11 November 10–11	12518
Ear, Nose, and Throat Devices Panel	March 19 June 18 September 17	12522
Gastroenterology-Urology Devices Panel	April 22–23 July 29–30 November 18–19	12523
General and Plastic Surgery Devices Panel	June 16–18 August 19–20 November 15–16	12519
General Hospital and Personal Use Devices Panel	May 10–11 August 2–3 November 15–16	12520
Hematology and Pathology Devices Panel	January 19–20 April 12 July 12 September 15 December 15	12515
Immunology Devices Panel	April 9 July 16 October 15	12516
Microbiology Devices Panel	May 20–21 July 15–16 September 9–10	12517
Neurological Devices Panel	March 25–26 June 17–18 September 16–17 December 9–10	12513
Obstetrics-Gynecology Devices Panel	April 12–13 July 12–13 October 4–5	12524
Ophthalmic Devices Panel	January 12 March 11–12 May 3–4 July 22–23 September 23–24 November 18–19	12396
Orthopaedic and Rehabilitation Devices Panel	April 26–27 July 26–27 October 25–26	12521
Radiological Devices Panel	May 17 August 16 November 8	12526
National Mammography Quality Assurance Advisory Committee	June 7–8 November 8–9	12397
Technical Electronic Product Radiation Safety Standards Committee	September 15–16	12399
CENTER FOR VETERINARY MEDICINE		
Veterinary Medicine Advisory Committee	January 25–26	12548

Committee Name	Dates of Meetings	Information Line Code
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH		
Advisory Committee on Special Studies Relating to the Possible Long-Term Health Effects of Phenoxy Herbicides and Contaminants	April 28–29 September 28–29	12560
Science Board to the National Center for Toxicological Research	March 24–25	12559

Dated: February 22, 1999.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 99–5285 Filed 3–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–65]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Information Collection Requirements in Final Peer Review Organization Sanction Regulations 42 CFR 1004.40, 1004.50, 1004.60, and 1004.70;

Form No.: HCFA–R–65 (OMB# 0938–0444);

Use: The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act to create the Utilization and Quality Control Peer Review Organization (PRO) program. The PRO program replaced the existing Professional Standards Review Organization (PSRO) program and streamlined peer review activities. PROs will ensure that care provided to Medicare patients is reasonable, medically necessary, appropriate, of a quality that meets professionally recognized standards of care, and that inpatient services could not be more appropriately provided on an outpatient basis or in a different type facility;

Frequency: On occasion;

Affected Public: Not-for-profit institutions, and Business or other for-profit;

Number of Respondents: 53;

Total Annual Responses: 1,060;

Total Annual Hours: 22,684.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: February 25, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–5349 Filed 3–3–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–131]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Information Collection Requirements in 42 CFR, Section 411.408;

Form No.: HCFA–R–131 (OMB# 0938–0566);

Use: Section 9332 of the Omnibus Budget Reconciliation Act of 1986, requires physicians ''who do not accept payment on an assignment-related basis'' to refund to patients any amounts they collect for services denied under section 1862(a)(1) of the Social Security Act, as ''not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member.'' Refunds are not required in either of two circumstances. First, a refund is not required if the physician informs the